UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,606	06/08/2001	Min Lu	19603/2921 (CRF-D-2484A)	1604

21186 7590 07/30/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	11

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,606	LU ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Restriction Requirement

35 U.S.C. § 121

1. Acknowledgement is hereby made of receipt and entry of the response filed 22 April, 2002. Applicants are advised that the restriction requirement set forth in paper no. 7 improperly set forth the claimed inventions and has been vacated. A new restriction requirement, pursuant to 35 U.S.C. § 121, which properly sets forth the various inventions is set forth as follows:

a. Group I, claim(s) 1-13, drawn to a **human immunodeficiency virus type 1 (HIV-1)** trimeric envelope polypeptide, classified in class , subclass .

b. Group II, claim(s) 1-7, drawn to a **human immunodeficiency virus type 2 (HIV-2)** trimeric envelope polypeptide, classified in class , subclass .

c. Group III, claim(s) 1-7, drawn to a **simian immunodeficiency virus (SIV)** trimeric envelope polypeptide, classified in class , subclass .

d. Group IV, claim(s) 1-7, drawn to a **Moloney murine leukemia virus (Mo-MLV)** trimeric envelope polypeptide, classified in class , subclass .

e. Group V, claim(s) 1-7, drawn to an **influenza virus** trimeric envelope polypeptide, classified in class , subclass .

f. Group VI, claim(s) 1-7, drawn to an **Ebola virus** trimeric envelope polypeptide, classified in class , subclass .

g. Group VII, claim(s) 14-29, drawn to vaccine compositions and **methods of vaccinating** an individual by administering an **HIV-1** trimeric envelope polypeptide, classified in class , subclass .

h. Group VIII, claim(s) 14-17 and 24-28, drawn to vaccine compositions and **methods of vaccinating** an individual by administering an **HIV-2** trimeric envelope polypeptide, classified in class , subclass .

i. Group IX, claim(s) 14-17 and 24-28, drawn to vaccine compositions and **methods of vaccinating** an individual by administering an **SIV** trimeric envelope polypeptide, classified in class , subclass .

j. Group X, claim(s) 14-17 and 24-28, drawn to vaccine compositions and **methods of vaccinating** an individual by administering a **Mo-MLV** trimeric envelope polypeptide, classified in class , subclass .

k. Group XI, claim(s) 14-17 and 24-28, drawn to vaccine compositions and **methods of vaccinating** an individual by administering an **influenza virus** trimeric envelope polypeptide, classified in class , subclass .

l. Group XII, claim(s) 14-17 and 24-28, drawn to vaccine compositions and **methods of vaccinating** an individual by administering an **Ebola virus** trimeric envelope polypeptide, classified in class , subclass .

m. Group XIII, claim(s) 30-32 and 36-39, drawn to an **antibody** that **binds** to an **HIV-1** trimeric envelope **polypeptide** and methods of making said antibody, classified in class , subclass .[1]

n. Group XIV, claim(s) 33-35, drawn to a **method of detecting HIV-1** using an **antibody** that binds to an HIV-1 trimeric envelope polypeptide, classified in class , subclass .

o. Group XV, claim(s) 33-35, drawn to a **method of detecting HIV-2** using an **antibody** that presumably binds to an HIV-2 trimeric envelope polypeptide, classified in class , subclass .

p. Group XVI, claim(s) 33-35, drawn to a **method of detecting SIV** using an **antibody** that presumably binds to an SIV trimeric envelope polypeptide, classified in class , subclass .

q. Group XVII, claim(s) 33-35, drawn to a **method of detecting Mo-MLV** using an **antibody** that presumably binds to an Mo-MLV trimeric envelope polypeptide, classified in class , subclass .

r. Group XVIII, claim(s) 33-35, drawn to a **method of detecting the influenza virus** using an **antibody** that presumably binds to an influenza virus trimeric envelope polypeptide, classified in class , subclass .

s. Group XIX, claim(s) 33-35, drawn to a **method of detecting the ebola virus** using an **antibody** that presumably binds to an ebola virus trimeric envelope polypeptide, classified in class , subclass .

t. Group XX, claim(s) 40-44, drawn to a **method of inhibiting HIV-1 infectivity** through the administration of an **antibody** that binds to an HIV-1 trimeric envelope polypeptide, classified in class , subclass .

---

[1] Applicants are advised that if the claims are amended to read on antibodies that also bind to HIV-2, SIV, Mo-MLV, influenza virus, and Ebola virus trimeric envelope polypeptides as set forth in Groups II-VI, that each antibody will constitute an independent and distinct invention based upon the specificity and binding of that particular antibody.

u. Group XXI, claim(s) 40-42, drawn to a **method of inhibiting HIV-2 infectivity** through the administration of an **antibody** that presumably binds to an HIV-2 trimeric envelope polypeptide, classified in class , subclass .

v. Group XXII, claim(s) 40-42, drawn to a **method of inhibiting SIV infectivity** through the administration of an **antibody** that presumably binds to an SIV trimeric envelope polypeptide, classified in class , subclass .

w. Group XXIII, claim(s) 40-42, drawn to a **method of inhibiting Mo-MLV infectivity** through the administration of an **antibody** that presumably binds to an Mo-MLV trimeric envelope polypeptide, classified in class , subclass .

x. Group XXIV, claim(s) 40-42, drawn to a **method of inhibiting influenza virus infectivity** through the administration of an **antibody** that presumably binds to an influenza virus trimeric envelope polypeptide, classified in class , subclass .

y. Group XXV, claim(s) 40-42, drawn to a **method of inhibiting Ebola virus infectivity** through the administration of an **antibody** that presumably binds to an Ebola trimeric envelope polypeptide, classified in class , subclass .

z. Group XVI, claim(s) 45-47, drawn to a **drug screening method** for identifying HIV-1 inhibitors using an HIV-1 trimeric envelope polypeptide, classified in class , subclass .

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different viral envelope polypeptide (e.g., HIV-1, HIV-2, SIV, Mo-MLV, influenza virus, and Ebola virus) with disparate structures, functions, and physical properties. Because of the genetic unrelatedness of these various viruses, separate searches will be required.

4. Inventions VII-XII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward vaccination methodologies employing different viral envelope polypeptides (e.g., HIV-1, HIV-2, SIV, Mo-MLV, influenza virus, and Ebola virus) with disparate structures, functions, and physical properties. Because of the genetic unrelatedness of these various viruses, separate searches will be required for each group.

5. Inventions I-VI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different product (e.g., viral envelope polypeptide, antibody) with different structures, functions, physical properties, and uses. Accordingly, separate searches will be required for each invention.

6. Inventions XIV-XIX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward disparate viral (e.g., HIV-1, HIV-2, SIV, Mo-MLV, influenza, and Ebola) detection methodologies employing disparate immunological reagents. Separate searches will be required for each invention. Therefore, each invention is clearly drawn toward a different inventive concept.

7. Inventions XX-XXV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward disparate methods for the inhibition of viral infectivity employing antibodies with different viral (e.g., HIV-1, HIV-2, SIV, Mo-MLV, influenza, and Ebola) binding specificities. Accordingly, separate searches will be required for each invention.

8. Inventions VII-XII, XIV-XIX, XX-XXV, and XXVI are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groupings is directed toward a different scientific objective (e.g., method of vaccination against viral infection, method of detecting viral infection, method of inhibiting viral infection, and methods for identifying antiviral compounds) that employs different scientific reagents (e.g., antibodies, peptides, vaccine compositions) and protocols. Separate searches will clearly be required for each invention.

9. Inventions I-VI and XIV-XIX/XX-XXV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the various methodologies do not require the peptides of Groups I-VI.

10. Inventions I and VI-XII, II and VII/IX-XII, III and VII/VIII/X-XII, etc. are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the various methodologies neither require nor use the identified peptides.

11. Inventions I and VII/XXVI, II and VIII, III and IX, etc. are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, each of the identified peptides can be employed in a number of materially different processes such as the generation of immunological reagents, affinity purification assays, diagnostic assays, or drug screening assays.

12. Inventions XIII and XIV/XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of Group XIII can be employed in a number of materially different processes such as diagnostic assays, inhibitory assays, or affinity purification assays.

13. Inventions XIII and XV-XIX/XXI-XXV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the different

methodologies identified neither require nor use the antibody of Group XIII.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicants are also reminded that the claim language should be amended, where necessary, to reflect the election.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Correspondence

16. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

17. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday

from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

27 July, 2002